

REMARKS

Applicants respectfully request reconsideration of the present application in view of the following commentary.

I. Status of the Claims

Claim 1 has been amended to recite a “nanoparticulate” composition, with ample support in the specification, at page 7, paragraph [0018]. Claim 1 has also been amended to clarify that the surface stabilizer is associate with the surface of the benzoyl peroxide particles. Support is found at page 16, paragraph [0059]. Claims 18-55 were subjected to a restriction requirement and deemed withdrawn by the Examiner. Claims 56 and 57 have been added. Exemplary support for the new claims can be found in the original specification, for example, at page 12, paragraphs [0040] and [0043].

Because no new matter is introduced by way of this amendment, Applicants respectfully request entry of the amendment. Upon entry, claims 1-57 will be pending with claims 18-55 withdrawn.

II. Species Election

The Examiner imposed a species election requirement on the pending claims and contends that “claims 11 and 12 are withdrawn as being dependent from non-elected species” (Office Action, page 2, third paragraph). Applicants respectfully disagree.

In contrast to a restriction requirement, the administrative expediency of a species election comprehends the prospect that a reasonable number of additional species, presently “non-elected,” will be considered when a given species within a recited genus is deemed patentable. *See* MPEP § 809.02(a), ¶8.01. Accordingly, withdrawal of claims 11 and 12 is premature, pending a disposition pursuant to Section 809.02(a) of the MPEP.

III. Rejection of Claims under 35 U.S.C. § 103(a)

A. Rejection over Ramirez

Claims 1-10 are rejected under 35 U.S.C. 103(a) for alleged obviousness over U.S. Patent No. 5,632,996 to Ramirez *et al.* (“Ramirez”). Applicants respectfully traverse the rejection.

The claimed composition comprises particles of benzoyl peroxide having an effective average particle size of less than about 2000 nm and at least one surface stabilizer. By contrast, Ramirez teach a composition comprising benzoyl peroxide and a mixture of non-irritating long chain alkyl benzoates. Ramirez teaches neither a composition comprising benzoyl peroxide with an effective average particle size of less than about 2000 nm nor a surface stabilizer as recited in claim 1.

First, the Examiner fails to resolve the level of ordinary skill in the art when asserting that one of ordinary skill in the art would recognize particle size as a result effective variable. The Examiner acknowledges that Ramirez “does not teach...the specific particle size of the BP.” (Office Action, top of page 4). As cited by the Examiner, MPEP §2144.05 expressly states that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). The Examiner contends that one of ordinary skill in the art would recognize that the particle size recited in the claims “is a result effective variable which is a matter of *routine optimization*” (Office Action, page 4, first paragraph, emphasis added). The Examiner, however, fails to resolve or identify the level of ordinary skill in the art to support this assertion. Therefore, no *prima facie* case for obviousness has been made.

Second, contrary to the Examiner’s assertion, Ramirez does not disclose a surface stabilizer as claimed and defined in the present invention, and more particularly, does not teach that the surface stabilizer is associated with the particles of benzoyl peroxide as recited in amended claim 1. Not only does Ramirez fails to disclose the claimed particle size (a fact acknowledged by the Examiner), but Ramirez also fails to teach, disclose, identify, or appreciate the relationship between the particles of benzoyl peroxide and the surface stabilizer. For at least this reason, no *prima facie* case for obviousness has been made.

Finally, the Examiner has ignored the criticality of selecting a surface stabilizer of the invention. The Examiner implies that the applicant has failed to show the criticality of the surface stabilizer selection by stating that “absent any express teaching of the criticality of the surface stabilizers, claims 1 and 3 are *prima facie* obvious” The Examiner’s implication is in error as the specification clearly describes that “not every combination of surface stabilizer and active agent will result in a stable nanoparticulate composition” and that “[i]t was surprisingly discovered that stable nanoparticulate benzoyl peroxide formulations can be made” (page 8, paragraph [0024]). According to the specification, “the choice of a surface stabilizer for benzoyl peroxide is non-trivial and required extensive experimentation to realize a desirable formulation” (page 17, paragraph [0065]). The specification further provides representative examples of suitable surface stabilizers from the bottom of page 17 through page 22. Accordingly, the Examiner has ignored the Applicant’s showing of the criticality of the selection of surface stabilizers of the present invention.

In view of the foregoing discussion, the Applicants respectfully request withdrawal of the obviousness rejection over Ramirez.

B. Rejections over Ramirez in view of other references

Claims 1-10 and 14-16 are rejected under 35 U.S.C. 103(a) for alleged obviousness over Ramirez in view of U.S. Patent No. 5,719,197 to Kanios *et al.* (“Kanios”). In addition, claims 1-10 and 13-17 are rejected for alleged obviousness over Ramirez in view of Kanios, and further in view of U.S. Patent No. 5,399,353 to Bartnick *et al.* (“Bartnick”). Applicants respectfully traverse each rejection.

As explained in the foregoing paragraphs, the primary Ramirez reference is acknowledged as failing to teach or disclose a nanoparticulate benzoyl peroxide composition with an effective particle size of less than about 2000 nm or a surface stabilizer associated with the benzoyl peroxide particles as recited in amended claim 1. None of the secondary references, including the knowledge of one of ordinary skill in the art, compensates for the deficiencies of the primary reference. Therefore, claim 1 is nonobvious over the cited prior art. Accordingly, Applicants respectfully request withdrawal of rejections under 35 U.S.C. § 103.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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